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10/536,887	04/07/2006	Derek Robin Haisman	DAIRY88.009APC	8297
20995	7590	06/25/2009	EXAMINER	
KNOBBE MARLENS OLSON & BEAR LLP			HANLEY, SUSAN MARIE	
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FOURTEENTH FLOOR			ART UNIT	PAPER NUMBER
IRVINE, CA 92614			1651	
NOTIFICATION DATE	DELIVERY MODE			
06/25/2009	ELECTRONIC			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/536,887	<b>Applicant(s)</b> HAISMAN ET AL.
	<b>Examiner</b> SUSAN HANLEY	<b>Art Unit</b> 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 May 2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-35 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This application contains claims (34 and 35) that are drawn to "use". These claims are nonstatutory because they are reasonably interpreted as being directed to a product, a method of making and a method of use.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, drawn to a process comprising three steps to make a complex composition of carbohydrates.

Group II, claim(s) 21-30, drawn to a composition comprising a mixture of galactose, glucose, fructose, gluconic acid, unconverted lactose and non-lactose di- and oligosaccharides.

Group III, claim(s) 31, 34 and 35, drawn to a five step process for the production of crystalline galactose from a mother liquor.

Group IV, claim(s) 33-35, drawn to a composition comprising a mother liquor.

Group V, claim(s) 34-35, drawn to a method for using a mother liquor.

Group VI, claim(s) 32, drawn to crystalline galactose.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a three step process that involves hydrolysis, partial isomerism and partial oxidation for produce a composition of a complex mixture of carbohydrates.

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The special technical feature of Group II is a composition comprising a mixture of galactose, glucose, fructose, gluconic acid, unconverted lactose and non-lactose di- and oligo- saccharides.

The special technical feature of Group III is a five step method to produce only crystalline galactose by process steps that involve hydrolysis, partial isomerism, partial oxidation, production a mother liquor comprising galactose crystals and the reaction products and the recovery of galactose crystal from the mother liquor.

The special technical feature of Group IV is a composition that is a mother liquor that contains galactose crystals as well as other reaction products.

The special technical feature of Group V is a method of using a mother liquor.

The special technical feature of Group VI is a composition that consists of one component, crystalline galactose.

Groups I and III lack a corresponding special technical feature because they are drawn to process steps that produce a different composition. Group I is a three step process that produces a composition having at least five different components while Group III is directed to a five step process that includes crystallization and recovery steps to produce a single product, crystalline galactose.

Groups I and II lack a corresponding special technical feature because Group II is drawn to a composition of at least seven products that are carbohydrates. This group lacks the process steps of Group I which includes contacting reactants with either chemicals and enzymes to produce products that are then used for another reaction that uses different enzymes to produce a different product(s).

Groups V and I or III lack a corresponding special technical feature because because the steps of using a mother liquor are distinct compared to the steps required to make a mixture of carbohydrates or a single product, crystalline galactose.

Groups II, IV, and VI all lack a corresponding special technical feature because each group is drawn to a distinctly different composition. The composition of Group II is a mixture of at least seven different carbohydrates. Group VI consists of a single product, crystalline galactose. Group IV consists of a mixture of unspecified carbohydrates as well as crystalline galactose in a solution or a suspension that is a mother liquor.

Groups I and IV lack a corresponding technical feature because Group IV consists of a mother liquor product that is not produced by the method of Group I.

Groups I and VI lack a corresponding special technical feature because Group VI is drawn to a single product of crystalline galactose that is not the product of a three step method that produces a complex mixture of carbohydrates.

Groups II and III lack a corresponding special technical feature because Group II is a complex mixture of carbohydrates while Group III comprises method steps, reactant and reagents that are designed to make a single product, crystalline galactose.

Groups V and II, IV or VI lack a corresponding technical feature because Groups II, IV and VI comprise different compositions while Group V is drawn to method steps for using a composition of a mother liquor. The compositions lack steps for using a product.

Groups III and IV or VI lack a corresponding special technical feature because Groups comprises compositions that consist of chemical compound(s) while Group III is drawn to method steps that comprises reacting reactant(s) with chemical reagents or enzymes to produce products. Groups IV and VI lack the reactant(s) and chemical and/or enzymes and the necessary steps to produce a product.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected:

A. Applicant is required to elect if the hydrolysis step of claim 1 is achieved by chemical, enzymatic means or in a bioreactor.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 13-16 correspond to the species.

The following claim(s) are generic: 1-12 and 17-20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Chemical reagents and enzymes work by different methods. Enzymes are catalysts while chemical reagents work by a chemical, non-catalytic mechanism.

If Applicant elects that the hydrolysis step of specie A is by enzymatic means, then Applicant is required to select the source of the specie of the microorganism from which the enzymes originates (claims 15 and 16).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 15 and 16 correspond to the species

The following claim(s) are generic: 1-12 and 17-20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The different species of microorganisms have different biological identifying characteristics.

B. Applicant is required to elect if the isomerism is by enzymatic or non-enzymatic means.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 17 and 18 correspond to the species

The following claim(s) are generic: 1-16, 19 and 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Enzymatic methods require an enzyme as a catalyst while non-enzymatic methods require some other non-enzyme reagent.

If Applicant elects an enzymatic means in specie B above, then Applicant is required to elect the specie of the source of the glucose isomerase (claim 18).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 18 corresponds to the species

The following claim(s) are generic: 1-17, 19 and 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of microorganism has different biological identifying characteristics.

C. Applicant is required to elect if the oxidation is by enzymatic or non-enzymatic means.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 19 and 20 the species

The following claim(s) are generic: 1-18.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Enzymatic methods require an enzyme as a catalyst while non-enzymatic methods require some other reagent.

If Applicant elects an enzymatic means in specie C above, then Applicant is required to elect the specie of the source of the oxidase AND the source of the catalase (see claim 20 for both elections).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 20 correspond to the species.

The following claim(s) are generic: 1-19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each specie of microorganism has different biological identifying characteristics.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651